16. The packaging system of claim 10 comprising a layer within a surface encompassed [the area which is enclosed] by the sealing area [layer], said [enclosed] layer being able to enter [entering] into interaction with the packaged product.

17. The packaging system of claim 16 wherein the encompassed [enclosed] layer is formed by a moisture absorbent layer.

REMARKS

Claims 9-17 are pending in the instant application. Claims 9-17 have been rejected. Claims 9, 13 and 15-17 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims under 35 U.S.C. § 112

Claims 9-17 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 has been amended to clarify the invention and to remove the limitation "such as transdermal therapeutic systems", as supported throughout the specification. Claim 15 has been amended in accordance with the Examiner's comments to further clarify the invention.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the above remarks and amendments to the claims.

II. Rejection of Claims under 35 U.S.C. § 103(a)

Claims 9-12 and 14 have been rejected under 35 U.S.C. §103(a) as unpatentable over Wardwell (U.S. Patent 3,938,659) in view of Hunt et al.(U.S. Patent 5,077,104). The Examiner has rejected claims 13 and 15 as being unpatentable over Wardwell in view of Hunt et al. as applied to claims 9-12, and further in view of Flieger, (U.S. Patent 5,447,772). Further, the Examiner has rejected claims 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Wardwell in view of Hunt et al. as applied to claims 9-12 and 14, and further in view of Wilking, (U.S. Patent 5,698, 217). Applicants respectfully traverse these rejections.

In accordance with Section 706.02(j) of the M.P.E.P., to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach all or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not found in Applicants' disclosure.

Wardwell teaches a bonding system particularly suited for packaging sterilized products such as sterile surgeons' gloves, masks and surgical dressings, see column 1, lines 5-15; column 3, lines 60-65. Wardwell teaches the use of frangible bonds to produce peelable bonding systems, which when opened allow the products enclosed within a paper package to remain sterile. Wardwell teaches a blush lacquer, used in conjunction with a layer of adhesive material to produce bonds that rupture through the blush lacquer without picking fibers from the paper. Wardwell does not teach a packaging system for pharmaceuticals comprising a barrier layer *on the product side* to which barrier layer there is

applied a heat sealing layer. Wardwell does not teach a barrier layer comprising aluminum.

Hunt et al. teach laminates of: (1) an aluminum foil or aluminum layer as a degradation agent barrier layer; and (2) a nicotine barrier layer for nicotine packaging materials. Hunt et al. do not teach the use of a *thin* printable active-ingredient resistant heat seal layers using printable lacquer on its application layers, as required by Applicants' invention. Hunt et al. teach a nitrile rubber modified acrylonitrile-methyl acrylate copolymer as the example of the preferred material for the sealing layer. As exemplified in Example 2, the preferred thickness of the sealing layer is 1.5 mil., also see column 3 lines 54-60. A printable heat seal layer is not taught by Hunt et al.

Applicants teach a sealing medium for composite packaging materials with volatile active ingredients. Applicants teach a barrier layer on the product side to which barrier layer there is applied a liquid phase printable heat seal layer. Applicants teach a barrier layer in claim 14 as comprising aluminum. Applicants' heat seal lacquer is applied from a liquid phase with a maximum thickness of 15 g/m^2 weight per unit area, the seal layer is applied via a conventional printing method, the packaging system is heat-activated to seal the package. Applicants teach extremely

thin seal layers using the lacquer in a printing process to designated full or partial areas of composite packaging materials.

There is no suggestion in Wardwell or Hunt et al. either alone or combined to modify their teachings to arrive at Applicants' invention. A person skilled in the art would not be motivated to use the printable lacquer useful in forming the frangible bonds of Wardwell's teaching with the barrier layers of Hunt. There is no motivation to combine the two teachings to arrive at Applicants' invention.

Also, Flieger teaches a *resealable* packaging system wherein the heat sealing layer may comprise an ethylene/methacrylic acid dispersion. However, Flieger does not supply the motivation to combine its teachings with the teachings of Wardwell and Hunt to arrive at Applicants' invention. Flieger teaches a seal that may be open and resealed, which is inapposite to Applicants' invention. One skilled in the art would not look to Flieger's teachings to suggest a suitable heat seal layer composition for a non-resealable seal. Therefore, there is no motivation to combine the teachings of Flieger with those of Wardwell, and Hunt et al. to arrive at Applicants' invention.

Claims 13 and 15 have been amended to clarify the invention as supported throughout the specification and at page 2, last

paragraph. The forestated remarks and amendments are believed to moot the rejection of claims 13 and 15 as stated with regard to Flieger.

The Examiner suggests that claims 16 and 17 are made obvious by the combined teachings of Wardwell, in view of Hunt et al. and Wilking. The Examiner suggests that both Wardwell and Wilking teach a sealed packaging system for pharmaceuticals and Wilking provides a packaging system which prevents degradation of pharmaceuticals from moisture, thus making it obvious to modify the teachings to result in Applicants' invention. Applicants respectfully traverse this rejection.

Claims 16 and 17 have been amended as supported in specification and at page 3, first paragraph. Claims 16 and 17 both depend from claim 9. As described in detail above, it would not be obvious to use a barrier layer on the product side of a packaging system, with an active ingredient resistant sealing layer being applied from a liquid phase via a printing method, as described in claim 9. Also, neither reference provides the teaching or suggestion to further comprise a layer encompassed by the sealing layers in the heat seal area, which may be a moisture absorbent layer. Neither Wardwell nor Hunt et al. alone or in

combination provide the teaching, suggestion or motivation to arrive at the present invention.

Further, Wilking does not provide the required teaching. Wilking describes a desiccant package for transdermal therapeutical systems (TTS) with a special desiccant compartment. The desiccant compartment is not a layer in the TTS. The desiccant is simply a part of a transdermal drug packaging unit that holds a removable drug product.

Applicants' invention teaches a packaging system comprising a layer within the area which is encompassed by the printable sealing layer. The layer may be a moisture absorbent layer. Neither Wardwell, Hunt et al., nor Wilking alone or in combination teach or suggest all of the limitations of claims 16 and 17. None of the cited references teach a distinct layer encompassed by the seal layer. There is no suggestion in the references singularly or combined that a layer could be encompassed by the sealing layer or that the encompassed layer could be a moisture absorbent layer.

III. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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